

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Petition to Revoke the GRAS)
Status of Salt, to Set Ceilings)
on the Amount of Sodium)
in Processed Foods, to Require)
a Health Warning on Packaged)
Salt, and to Reduce the Daily Value)
for Sodium)

Docket No. _____

submitted by the

CENTER FOR SCIENCE IN THE PUBLIC INTEREST

November 8, 2005

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2005P-0450

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I. Preliminary Statement

Almost 25 years ago the Food and Drug Administration (“FDA”) decided that a reduction in salt (sodium chloride) and sodium consumption would reduce the frequency of hypertension. However, the FDA did not set limits on the amount of salt in processed foods because it wanted to see if voluntary actions by the food industry would lead to a reduction in salt consumption.¹ That effort failed miserably: Per capita sodium consumption has increased by about 10 percent since that FDA decision (see section III.G. below).

The *Dietary Guidelines for Americans 2005* (published jointly by the Department of Health and Human Services and the Department of Agriculture) recommends that Americans consume less salt because reducing salt intake reduces blood pressure in many people, thereby lowering an individual’s risk of coronary heart disease, stroke, congestive heart failure, and kidney disease.² That recommendation echoes the conclusion of both a 2002 report by the National Institutes of Health and a 2004 report by the Institute of Medicine of the National Academies.³ Older persons, African Americans, and people with high blood pressure tend to be especially sensitive to the blood pressure-raising effects of salt.⁴ While small amounts of sodium occur naturally in practically all foods, salted processed foods provide the great majority of salt that Americans consume.⁵

Congress is so concerned about the public health risks of excessive salt consumption that in June 2005 the House of Representatives’ Committee on Appropriations said that it

1. 47 Fed. Reg. 26590 (June 18, 1982) at 26593.

2. *Dietary Guidelines for Americans 2005* (Department of Health and Human Services and Department of Agriculture 2005) at 39-40.

3. *Primary Prevention of Hypertension: Clinical and Public Health Advisory from the National High Blood Pressure Education Program* (National Institutes of Health National Heart, Lung and Blood Institute 2002) at 3-4; *Dietary Reference Intakes, Water, Potassium, Sodium, Chloride, and Sulfate* (Institute of Medicine of the National Academies 2004) at 6-112. See also “The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and the Treatment of High Blood Pressure,” *Journal of the American Medical Association* (May 21, 2003) at 2562, 2564, 2570.

4. *Dietary Guidelines for Americans 2005* (Department of Health and Human Services and Department of Agriculture 2005) at 41; *Dietary Reference Intakes, Water, Potassium, Sodium, Chloride, and Sulfate* (Institute of Medicine of the National Academies 2004) at 6-2.

5. *Dietary Guidelines for Americans 2005* (Department of Health and Human Services and Department of Agriculture 2005) at 40; *Dietary Reference Intakes, Water, Potassium, Sodium, Chloride, and Sulfate* (Institute of Medicine of the National Academies 2004) at 6-43-44.

“encourages the Secretary [of Health and Human Services] to focus on ways – including both voluntary actions by the food industry and regulatory actions by the Food and Drug Administration and the Department of Agriculture – to reduce salt in processed and restaurant foods.”⁶

II. Action Requested

The Center for the Science in the Public Interest⁷ (“CSPI”) requests⁸ that the FDA initiate a rulemaking: (1) to revoke the Generally Recognized as Safe (“GRAS”) status of salt,⁹ (2) to amend any prior sanctions for salt, (3) to require food manufacturers to reduce the amount of sodium in all processed foods¹⁰ – both packaged foods sold at retail and foods sold directly to

6. H.R. Rept. 109-143. 109th Cong. (2005) at 142. Because the United States Department of Agriculture (“USDA”) regulates the labeling of meat and poultry products, many of which are high in sodium, CSPI is providing a copy of this petition to USDA and urging it to take actions similar to those requested here.

7. Petitioner Center for Science in the Public Interest, a non-profit organization based in Washington, D.C., is supported largely by 900,000 members in the United States and Canada who subscribe to its *Nutrition Action Healthletter*. CSPI has been working to improve the nation’s health through better nutrition and safer food since 1971.

8. This petition is submitted pursuant to section 4(e) of the Administrative Procedure Act, 5 U.S.C. 553(e), and 21 C.F.R. 10.25 and 10.30.

9. 21 C.F.R. 182.1(a).

10. There is no need to amend those standards of identity that have salt as a mandatory ingredient, as none contains a minimum amount of salt: asiago fresh and asiago soft cheese, 21 C.F.R. 133.102(b), blue cheese, 21 C.F.R. 133.106(a)(2), brick cheese, 21 C.F.R. 133.108(a)(3), cheddar cheese, 21 C.F.R. 133.113(a)(3), colby cheese, 21 C.F. 133.118(b), washed curd and soaked curd cheese, 21 C.F.R. 133.136(a)(3), edam cheese, 21 C.F.R. 133.138(a)(3), gorgonzola cheese, 21 C.F.R. 133.141(a)(2), granular and stirred curd cheese, 21 C.F.R. 133.144(a)(3), hard grating cheeses, 21 C.F.R. 133.148(b), gruyere cheese, 21 C.F.R. 133.149(a)(3), hard cheeses, 21 C.F.R. 133.150(b), limburger cheese, 21 C.F.R. 133.152(a)(3), parmesan and reggiano cheese, 21 C.F.R. 133.165(b), romano cheese, 21 C.F.R. 133.183(b), roquefort cheese, 21 C.F.R. 133.184(a)(2), samsoe cheese, 21 C.F.R. 133.185(a)(3), sap sago cheese, 21 C.F.R. 133.186(a)(2), skim milk cheese for manufacturing, 21 C.F.R. 133.189(b), swiss and emmentaler cheese, 21 C.F.R. 133.195(a)(3), self-rising flour, 21 C.F.R. 137.180(a), and self-rising white corn meal, 21 C.F.R. 137.270(a).

restaurants,¹¹ (4) to require health messages on retail packages of salt one-half ounce or larger,¹² and (5) to reduce the Daily Value for sodium from its current level of 2,400 mg¹³ to 1,500 mg.

An overall 50 percent reduction in sodium over, say, 10 years would help reduce average per capita daily sodium consumption from its current level of about 4,000 milligrams (“mg”) to 2,000 mg, which is less than the 2,300 mg¹⁴ recommended by the *Dietary Guidelines for Americans 2005* for young non-hypertensive white adults but more than the 1,500 mg recommended for people with hypertension, blacks, and middle-and older-aged adults.¹⁵ (We note that even the 1,500 mg level is more than the 1,300 mg level that the Institute of Medicine considers an Adequate Intake for people 50 years through 70 and the 1,200 mg Adequate Intake for those 71 and older [see section VI].)

That reduction could be accomplished through various routes. One way would be for the FDA to set ceilings for added salt for different categories of food—especially the biggest sources of dietary sodium and the highest-sodium foods—so that the overall reduction, based on consumption patterns, would be a 50 percent overall reduction in total sodium.^{16, 17} As discussed

11. For example, McDonald’s and Burger King each have salt in their precooked french fries, and additional salt is then added in the restaurant. McDonald’s has about 30 mg of sodium in its precooked fries, and 110 mg of salt is added in their restaurants; Burger King has about 240 mg of sodium in its precooked fries, and 140 mg of salt is added in their restaurants. *The Wall Street Journal* (August 17, 2005) at D1. We propose regulating the salt in the precooked fries.

12. The message, for example, could say “Salt promotes heart disease. Use less. Try using half as much salt as called for in recipes.” The British government uses the phrase “Salt is bad for your heart.” Salt labels already contain other health information. For example, one brand of iodized salt says that one serving contains 25 percent of the Daily Value of sodium and that “this salt supplies iodide, a necessary nutrient.” The FDA could conduct consumer surveys to ensure that the new health message would not confuse consumers in light of the other information already contained on the salt package label.

13. 21 C.F.R. 101.9(c)(9).

14. *Dietary Guidelines for Americans 2005* (Department of Health and Human Services and Department of Agriculture 2005) at 40.

15. *Dietary Guidelines for Americans 2005* (Department of Health and Human Services and Department of Agriculture 2005) at 40.

16. Small studies indicate that about 12 percent of sodium is naturally occurring in milk, seafood, and other foods; about 11 percent is added during cooking or at the table; and about 77 percent is added during processing. Though monosodium glutamate, sodium phosphate, and other additives contribute some of that added sodium, nearly all comes from sodium chloride. Mattes RD, Donnelly D. Relative contributions of dietary sodium sources. *J Am Coll Nutr.* 1991; 10:383–93. Cotton PA, Subar AF, Friday JE, et al. Dietary sources of nutrients among US adults, 1994 to 1996. *J Am Diet Asso.* 2004; 104:921–30.

17. Procedurally, the FDA could propose a regulation (or issue an advance notice of proposed rulemaking) along the lines of the British approach, which divides the food supply into dozens of categories, each with a targeted sodium level; the public could comment on the proposed levels.

below in section VII, the British government has adopted that approach, aiming for a 33 percent reduction in sodium over five years. Considering the wide variation in salt levels of different brands within a particular category, some companies would have to achieve major reductions, while others would have to make modest or no reductions.

III. Factual Background

A. In 1978 CSPI petitioned the FDA to take several steps to restrict the amount of salt and sodium in packaged foods.

In July 1978, CSPI (with Georgetown University School of Law's Institute for Public Interest Representation doing the legal work) filed two petitions that called on the FDA to set ceilings (tolerances in FDA terminology) for sodium in processed foods, to reclassify salt (sodium chloride) from GRAS to food additive status, and to require sodium labeling on packaged foods. We also suggested that the FDA require a special symbol on the labels of high-sodium foods.

B. In 1979 the Federation of American Societies for Experimental Biology told the FDA that salt consumption should be lowered in order to reduce the incidence of hypertension.

In 1979 the Federation of American Societies for Experimental Biology ("FASEB") submitted to the FDA its final report on the safety of salt as an ingredient. (The FDA had held a public hearing on the FASEB's tentative report in 1978.) The FASEB concluded that "the evidence on sodium chloride [salt] is insufficient to determine that the adverse effects reported are not deleterious to the health of a significant proportion of the public when it is used at levels that are now current and in the manner now practiced."¹⁸ The FASEB also said that it "believes that a reduction of sodium chloride consumption by the population will reduce the frequency of hypertension....It is the prevalent judgment of the scientific community that the consumption of sodium chloride in the aggregate should be lowered in the United States. The [FASEB] agrees

Alternatively, the FDA could announce its goal of reducing overall consumption of sodium by 50 percent and ask companies if such (or greater) reductions are feasible in various food categories. (Some reductions may not be possible. For example, milk and seafood naturally contain sodium; reducing salt excessively in some foods might jeopardize health by facilitating the growth of pathogens).

FDA could set limits on the total sodium content of foods, rather than just sodium chloride. That would facilitate enforcement. Limits on total sodium would recognize the amounts of unavoidable naturally occurring sodium in various foods, as well as the sodium contributed by other additives.

Restaurants and other food service institutions have become increasingly important sources of sodium. For chain restaurants that sell standardized, easily categorized foods, such as French fries and Italian dressing, the FDA could apply limits. However, that approach is not applicable to many non-standardized dishes. In those situations, the FDA should use its influence to encourage restaurant cooks voluntarily to gradually use less salt.

18. *Evaluation of the Health Aspects of Sodium Chloride and Potassium Chloride as Food Ingredients*, Federation of American Societies for Experimental Biology (1979) at 36.

and favors development of guidelines for restricting the amount of salt in processed foods, a major contributor of dietary sodium.”¹⁹

C. In 1981 CSPI petitioned the FDA to take additional measures to reduce sodium consumption.

In March 1981, CSPI sent to the Secretary of Health and Human Services an informal petition from 5,769 health professionals and students urging the FDA to limit sodium in processed foods. In December 1981, CSPI formally petitioned the FDA to require warning labels on packages of salt weighing half an ounce or more.

D. In 1982 the FDA deferred action on setting ceilings on the amount of salt in packaged foods in order to see if voluntary actions by the food industry would reduce sodium consumption.

In June 1981 the Secretary of Health and Human Services and the FDA Commissioner met with the food industry to discuss what steps the industry could take to reduce salt consumption.²⁰ A year after that meeting the FDA published a proposed rule amending its labeling regulations to encourage the voluntary labeling of the amount of sodium in processed foods.²¹ The FDA said that it agreed with the FASEB that a reduction of salt consumption would reduce the frequency of hypertension,²² but said that it was deferring action on the GRAS status:

... because the Commissioner believes that a voluntary program will produce the desired results with less regulatory burden. Moreover, the food industry is in the best position to reduce sodium levels in processed food and to provide more information to consumers. The Commissioner believes that the industry should be given a chance to do so.²³

On the same day the FDA also published a notice announcing that it would defer revising the GRAS status of salt.²⁴

The FDA further said “The agency wishes to emphasize that *if there is no substantial reduction in the sodium content of processed foods* and if the information sodium labeling is not

19. *Id.* at 35, 36.

20. 47 Fed. Reg. at 26592.

21. 47 Fed. Reg. 26580 (June 18, 1982).

22. 47 Fed. Reg. 26590 (June 18, 1982) at 26592.

23. 47 Fed. Reg. at 26594.

24. 47 Fed Reg 26590 (June 18, 1982).

adopted after a reasonable time period, *FDA will consider additional regulatory options, including proposing a change in salt's GRAS status.*"²⁵ (emphasis added)

E. In 1984 a federal District Court said that the FDA must reconsider the GRAS status of salt after it had assessed the impact of its 1982 decisions.

Nine months after the FDA's decisions, CSPI sued the FDA in federal District Court, challenging both the agency's failure to require mandatory sodium content labeling and its deferral of a decision on the GRAS status of salt. In 1984 the court dismissed the complaint, concluding that there was a rational basis for both decisions.²⁶ However, noting that the FDA had said "that it will consider proposing a change in the GRAS status of salt if there is no substantial reduction in the sodium content of processed food and if information sodium labeling is not adopted after a reasonable period of time," the court said that "the FDA *must* make a decision on the GRAS status of salt after it has completed its review, *i.e.*, after the voluntary programs have been in effect for a reasonable period of time and FDA has had an opportunity to assess their impact and to review new scientific studies on sodium chloride consumption."²⁷ (emphasis added)

F. Beginning in 1994 packaged foods have had to disclose the amount of sodium both in amount and as a percentage of a Daily Value.

Pursuant to the Nutrition Education and Labeling Act of 1990 ("NLEA"), the FDA has required since 1994 that packaged foods disclose the amount of sodium per serving both in milligrams and as the percentage of a recommended Daily Value ("DV") of 2,400 mg.

In its final food labeling regulations, published in 1993, the FDA took a conservative approach towards protecting the public health. Some commentators on the proposed rule said there should be no mandatory sodium content declaration because there was allegedly a "debate within the scientific community as to whether it was necessary and appropriate for the general population to reduce its sodium consumption. Further, those comments stated that control of sodium intake was only relevant for those segments of the population that are "sodium sensitive."²⁸ The FDA rejected that argument, saying "it would be prudent for the general population to reduce sodium consumption, even though not all people display increased blood pressure in response to high sodium intakes."²⁹

25. 47 Fed. Reg. at 26593.

26. *Center for Science in the Public Interest v. Novitch*, Food, Drug & Cosmetic L. Rep. (CCH) par 38,275 (D.D.C. June 11, 1984).

27. *Id.* at 9.

28. 58 Fed. Reg. 2066 (January 6, 1993) at 2094.

29. *Id.*

In 1991 the FDA proposed a regulation that, in pertinent part, set a DV for sodium at 2,400 mg. The FDA said it was suggesting that level because “the FDA has long recognized that sodium is a risk factor contributing to high blood pressure” and that 2,400 mg “represents a 20 to 60 percent reduction below current estimates of sodium intake (3,000 to 6,000 mg per day).”³⁰ (references omitted)

In its final regulation in 1993 the FDA rejected both: (a) comments that the DV should be below 2,400 mg “to better protect millions of Americans, especially older citizens, with hypertension” and (b) comments that the DV should be higher than 2,400 mg.³¹ The FDA said “2,400 mg is consistent with other Federal agency recommendations and with current public health agency policies to moderate or reduce sodium intake. Furthermore, the 2,400 mg level is a feasible goal because sodium in food is primarily present as added salt...”³²

The FDA also concluded in 1993 that “based on the totality of the scientific evidence, there is significant scientific agreement among qualified experts that diets low in sodium may help lower blood pressure in many people,” and so the FDA decided to permit a health claim that diets low in sodium are associated with a low prevalence of hypertension or high blood pressure.³³

G. Dietary sodium comes mostly from processed foods, and consumption has increased substantially since 1982.

Some of the sodium in our food supply, especially in milk, occurs naturally. But the vast majority of sodium comes from processed foods. Indeed, it is estimated (based on a relatively small survey) that about 75 percent of dietary sodium comes from processed foods and foods eaten outside the home.³⁴

The government conducts major dietary surveys to determine consumption of sodium, as well as other nutrients, in the general population and various subgroups: The National Health and Nutrition Examination Survey (“NHANES”), which is conducted by the U.S. Department of Health and Human Services, and the Continuing Study of Food Intakes by Individuals

30. 56 Fed. Reg. 60825 (November 27, 1991) at 60835.

31. 58 Fed. Reg. at 2223-2224.

32. 58 Fed. Reg. at 2224.

33. 58 Fed. Reg. 2820 (January 6, 1993). This regulation is now codified at 21 C.F.R. 101.74. Two model claims permitted by the FDA are: “Diets low in sodium may reduce the risk of high blood pressure, a disease associated with many factors.” and “Development of hypertension or high blood pressure depends on many factors. [This product] can be part of a low sodium, low salt diet that might reduce the risk of hypertension or high blood pressure.” 21 C.F.R. 101.74(e).

34. *Dietary Guidelines for Americans 2005* (Department of Health and Human Services and Department of Agriculture 2005) at 40.

(“CSFII”), which was conducted by the U.S. Department of Agriculture. According to NHANES, average daily sodium consumption is substantially higher than recommended and has increased over the years, rising from about 2,800 mg in 1976–80 to about 3,400 mg in 1999–2000 (the latest period for which survey data are available) (see attachment 1). But dietary-recall surveys typically underestimate actual consumption, partly because people do not accurately remember or report what they eat and partly because the major surveys do not seek to assess how much salt people add at the table. Therefore, people are actually consuming even more sodium than surveys indicate.³⁵

Another way to assess sodium intake is to measure urinary sodium excretion. That approach, while more accurate than dietary surveys, is more expensive so sample sizes are not as large or representative of the entire population. Several such studies found sodium intakes of 4,000 mg per day (averaging men and women).³⁶ (Even measurements of urinary sodium may underestimate actual intake slightly, because some sodium is lost through sweat and stools.) The higher sodium intakes in the two urinary excretion studies are not surprising considering that people typically underestimate their consumption in dietary-recall surveys like NHANES and CSFII.

The reason for the increase in salt consumption is *not* that we are using our salt shakers more often. While CSPI is not aware of data on per capita purchases of table salt in the United States, in the United Kingdom household consumption of salt declined by more than two-thirds between 1960 to 2000.³⁷ With people in both countries cooking less and eating more packaged and restaurant foods, it is likely that a similar decline occurred in the United States.

One reason for increased sodium consumption is that people are consuming more calories, that is, more food. According to the NHANES surveys, caloric intake has increased by almost 10 percent from 1,980 calories in 1976–80 to 2,150 calories in 1999–2000 (see attachment 1).

While the methods used in those surveys vary, and dietary surveys typically underestimate intakes, it is clear that industry’s voluntary efforts have not led to reductions in

35. A cruder estimate of salt, and sodium, intake is from national production of food-grade salt. According to the Salt Institute, between 1978 and 1983, per-capita daily salt production declined from about 4,400 mg of sodium to about 3,800 mg; it then increased steadily by about 50 percent in 1998, to about 5,700 mg (there are no comparable data after 1999).

36. Zhou BF, Stamler J, Dennis B, et al. Nutrient intakes of middle-aged men and women in China, Japan, United Kingdom, and United States in the late 1990s: The INTERMAP study. *J Hum Hypertens*. 2003; 17:623–30. Kumanyika SK, Cook NR, Cutler JA, et al. Sodium reduction for hypertension prevention in overweight adults: further results from the Trials of Hypertension Prevention Phase II. *J Hum Hypertens*. 2005; 19:33–45.

37. Department for Environment, Food and Rural Affairs. National Food Survey 2000. London: The Stationery Office, 2001, and previous editions. Household consumption of table salt, 1960-2000, Great Britain. www.heartstats.org (British Heart Foundation) (accessed Sept. 22, 2004).

sodium intake and that sodium levels are even higher than they were in the early 1980s. (Despite the advent of mandatory nutrition labeling in 1994, average per capita daily consumption of sodium has remained at about 3,400 mg between 1988-94 and 1999-2000 (see attachment 1).)

H. In 2005 a federal Court of Appeals said it did not have jurisdiction to decide whether to order the FDA to reconsider the GRAS status of salt because CSPI had not filed a petition with the FDA.

In February 2005 CSPI petitioned a Court of Appeals to issue a writ of mandamus compelling the FDA to complete its review of the GRAS status of salt and either affirm its current status or declare it a food additive. The Court dismissed the petition, saying it had no jurisdiction because CSPI “did not seek a remedy from the [agency] or initiate any proceeding in [the] agency before resorting to this court.”³⁸

I. In 2005 the FDA reaffirmed its earlier conclusion that sodium has an adverse impact on cardiovascular disease.

In September 2005 the FDA published a final rule on how much sodium could be in a food that claims on its label that it is “healthy.”³⁹ One of the commentators on the proposed rule claimed that “there was no evidence that restricting sodium consumption will result in improved cardiovascular health outcomes.”⁴⁰

The FDA rejected this claim. The FDA referred to the 2004 Institute of Medicine study, the NIH DASH-Sodium study (discussed below in section IV.), and *The Dietary Guidelines for Americans 2005*, and concluded that these studies “demonstrate that the intake of excess sodium in the diet is indeed a public health issue....there is ample evidence that sodium has an adverse impact on cardiovascular disease, particularly hypertension, and that as a consequence, the amount of sodium in an individual food or meal type product should be controlled in order for such a product to be labeled as ‘healthy’.”⁴¹

IV. Reducing Sodium Consumption Lowers Blood Pressure

Sodium is of concern primarily because it increases blood pressure, but it may cause harm through other unidentified mechanisms. High blood pressure is extraordinarily common –

38. *In Re Center for Science in the Public Interest*, No. 05-1057 (D.C. Cir. 2005) *per curiam* (citing *In Re Tennant*, 359 F.3d 523, 528 (D.C. Cir. 2004)).

39. 70 Fed. Reg. 56828 (September 29, 2005). The final rule permits a food label to say the food is “healthy” if its sodium level does not exceed 480 mg per serving for individual foods and 600 mg per serving for meals and main dishes.

40. 70 Fed. Reg. at 56830.

41. 70 Fed. Reg. at 56831, 56835.

and becoming even more so. The 1999-2000 NHANES study found that 31.3 percent of Americans have high blood pressure, up from 28.9 percent in 1988-94. About 65 million American adults have high blood pressure, a 30 percent increase over the 50 million people with hypertension in 1988-94. Another 45 million people have pre-hypertension.⁴²

Numerous studies have quantified the effect of sodium on blood pressure. Examples include:

- One large 2004 study conducted in Europe showed convincingly that the higher the sodium intake, the higher the blood pressure and risk of hypertension.⁴³ The researchers found that people who consume about 5,000 mg of sodium per day have twice the risk of hypertension as those who consume 1,800 mg. They conclude that “even modest...differences in sodium intake are associated with blood pressure differences of clinical and public health relevance.”
- The Dietary Approaches to Stop Hypertension study – DASH–Sodium – was designed to definitely evaluate the link between salt and blood pressure. The carefully controlled study, published in 2001, tested the effects on blood pressure of three levels of sodium intake and two different diets – a typical American diet and a more healthful one.⁴⁴ The healthful diet consisted largely of fruits, vegetables, grains, low-fat dairy foods, poultry and meat, fish, beans, and nuts. The “high” sodium level (3,270 mg) contained about one-fifth less sodium than the average American diet. The “intermediate” level (2,460 mg) was one-fourth lower than the high, and the “low” (1,500 mg) level contained about half as much sodium as the high. Participants were given all meals of known nutrient content to help them adhere to the diet. The study found significant benefits both from eating a healthy diet (keeping sodium constant) and from eating less sodium. Combining both measures provided a double benefit. For instance, going from the high to the intermediate level of sodium reduced systolic blood pressure by 2.1 mm Hg. Dropping to the low-sodium diet decreased the subjects’ blood pressure another 4.6 mm Hg (total of 6.7 mm Hg). On the other hand, once the subjects were eating a healthy diet, the added benefit of going from high to low sodium was less: 3 mm Hg. Switching from the typical diet to the DASH diet, but keeping sodium at the high level, decreased blood pressure by 5.9 mm Hg. Also, the benefit from a given reduction of sodium increased as total sodium consumption decreased, so the greater the reduction in sodium, the greater the payoff. The maximum benefit came from switching from the high-sodium version of the normal diet to the low-sodium version of the DASH diet. That decreased systolic blood pressure by about 8.9 mm Hg. African

42. Chobanian AV, Bakris GL, Black HR, et al. The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. *JAMA*. 2003;289:2560-72. National Heart, Lung, and Blood Institute. NHLBI issues new high blood pressure clinical practice guidelines. (News release) May 14, 2003.

43. Khaw KT, Bingham S, Welch A, et al. Blood pressure and urinary sodium in men and women: the Norfolk Cohort of the European Prospective Investigation into Cancer (EPIC–Norfolk). *Am J Clin Nutr*. 2004; 80:1397–403.

44. Sacks FM, Svetkey LP, Vollmer WM, et al. Effects on blood pressure of reduced dietary sodium and the dietary approaches to stop hypertension (DASH) diet. *N Engl J Med*. 2001; 344:3–10.

Americans with hypertension and people over age 45 with hypertension benefitted the most from consuming less salt.⁴⁵ People under 45 without high blood pressure benefitted least (although a large percentage of those people will develop hypertension as they age). It is worth noting that subjects consumed the various diets for only four weeks at a time, and their blood pressure was still declining after four weeks.⁴⁶

- Trials of Hypertension Prevention (TOHP II) studied 1,100 moderately overweight, middle-aged adults with moderately elevated blood pressure.^{47, 48} Half of the participants were intensively counseled to reduce their sodium intake, but were not given low-sodium foods. After three years, the subjects were consuming an average of 24 percent (about 930 mg per day) less sodium than the control group. Their systolic pressure declined 1.7 mm Hg and their diastolic pressure 0.9 mm Hg; moreover, their incidence of hypertension dropped by 18 percent.

- Hypertension experts at NHLBI conducted a major meta-analysis that assessed the combined results of 32 clinical studies.⁴⁹ The researchers estimated that a reduction of 2,300 mg of sodium per day would reduce blood pressure by 1.9/1.1 mm Hg (systolic/diastolic) in people with normal blood pressure and 4.8/2.5 mm Hg in people with hypertension.

- One important study examined the effects of reducing sodium (with or without a weight-loss effort) in almost 1,000 people between the ages of 60 and 80 with elevated blood pressure.⁵⁰ The subjects managed to reduce their sodium intake by about 25 percent. Their blood pressure dropped by 2.6/1.1 mm Hg compared to the “usual care” (control) group. Combining weight loss with reduced sodium roughly doubled the declines in blood pressure.

45. GA, Vollmer WM, Sacks FM, et al. A further subgroup analysis of the effects of the DASH diet and three dietary sodium levels on blood pressure: results of the DASH Sodium Trial. *Am J Cardiol*. 2004; 94:222–7.

46. Obarzanek E, Proschan MA, Vollmer WM, et al. Individual blood pressure responses to changes in salt intake: Results from the DASH–sodium diet. *Hypertension*. 2003; 42:459–67.

47. Kumanyika SK, Cook NR, Cutler JA, et al. Sodium reduction for hypertension prevention in overweight adults: further results from the Trials of Hypertension Prevention Phase II. *J Hum Hypertens*. 2005; 19:33–45.

45. Cook NR, Kumanyika SK, Cutler JA, et al. Dose–response of sodium excretion and blood pressure change among overweight nonhypertensive adults in a 3-year dietary intervention study. *J Hum Hypertens*. 2005;19:47-54.

49. Cutler, JA, Follmann D, Allender PS. Randomized trials of sodium reduction: an overview. *Am J Clin Nutr*. 1997; 65(suppl):643S–51S.

50. Whelton PK, Appel LJ, Espeland MA, et al. Sodium reduction and weight loss in the treatment of hypertension in older persons (TONE). *JAMA*. 1998; 279:839–46.

V. Significantly Lowering Sodium Consumption Would Save Tens of Thousands of Lives Annually.

Scientists, with a few exceptions,⁵¹ agree that lowering sodium intake lowers blood pressure and that lowering blood pressure would prevent thousands of fatal heart attacks and strokes each year. Indeed, according to a meta-analysis of 61 studies, the lower an individual's blood pressure – at least down to 115/75 mm Hg – the lower the risk of stroke or heart attack.⁵² There was no “threshold” below which the risk did not decrease. Another large study found similar results when diastolic blood pressure ranged between 70 and 110 mm Hg.⁵³ Thus, while a diastolic blood pressure of 80 is often considered “normal,” it is not optimal. (The Yanomami Indians, a primitive tribe living in South America, has been reported to be free of hypertension. They have a median blood pressure of 95/61.⁵⁴)

Researchers have calculated the potential health benefits from lowering blood pressure. While their estimates vary, they all project major benefits and conclude that even small average reductions in a population's blood pressure would yield large benefits. The following examples indicate the magnitude of the likely benefits:

- The meta-analysis of 61 studies mentioned above concluded that a reduction of 10 mm Hg in systolic blood pressure or 5 mm Hg in diastolic (both challenging goals) could result over the

51. Several academics have opposed reducing sodium consumption in the general population, though they support reduced sodium intakes in the treatment of hypertensive individuals. They base their position on studies that are inconsistent with most of the research, or they argue that hypertension is best treated on an individual basis. McCarron DA. The dietary guideline for sodium: should we shake it up? Yes! *Am J Clin Nutr.* 2000; 71:1020-6; Alderman MH, Cohen H, Madhavan S. Dietary sodium intake and mortality: The National Health and Nutrition Examination Survey (NHANES I). *Lancet.* 1998; 351:881-5. Most hypertension experts, though, have concluded that the research the contrarians cite is either flawed, misinterpreted, or so fragmentary as not to negate the great body of well-done research that shows that salt tends to increase blood pressure and that high blood pressure is harmful to large segments of the population. Health experts have generally taken the position that even though some people are less sensitive to the effects of salt than others, treating or preventing a problem as widespread as hypertension needs to be undertaken on a public health (population) level, and not only by treatment of individuals by their physicians.

52. Prospective Studies Collaboration. Age-specific relevance of usual blood pressure to vascular mortality: a meta-analysis of individual data for one million adults in 61 prospective studies. *Lancet.* 2002; 360:1903-13.

53. MacMahon S, Peto R, Cutler J, et al. Blood pressure, stroke, and coronary heart disease. Part 1, prolonged differences in blood pressure: prospective observational studies corrected for the regression dilution bias. *Lancet.* 1990; 335:765-74.

54. Mancilha-Carvalho JJ, Souza e Silva NA. The Yanomami Indians in the INTERSALT study. *Arq Bras Cardiol.* 2003; 80:295-300.

long term in about a 40 percent lower risk of stroke death and about a 30 percent lower risk of death from coronary heart disease.⁵⁵

- A group of leading researchers estimates that a modest nationwide 3 mm Hg decrease in systolic blood pressure would result in 11 percent fewer strokes, 7 percent fewer coronary artery disease events, and 5 percent fewer deaths overall.⁵⁶ The latter percentage implies about 122,000 fewer deaths per year in the United States.
- Researchers using data from the Framingham Heart Study calculated the benefits of a 2 mm Hg decrease in diastolic blood pressure in white 35- to 64-year-old Americans.⁵⁷ They found that that decrease was associated with a 17 percent decrease in the prevalence of hypertension, a 15 percent decrease in the incidence of stroke and transient ischemic attacks (“mini-strokes”), and a 6 percent reduction in the incidence of coronary heart disease.
- In 1993, Jeremiah Stamler and his colleagues estimated that lowering the average systolic blood pressure in 35- to 59-year-old men from 130 to 120 mm Hg (an ambitious goal) would reduce mortality by 14 percent and increase life expectancy by 1.5 years.⁵⁸ For the middle-aged men they were considering, that reduction would save an estimated 30,000 lives per year.
- Two leading British researchers, Feng Jun He and Graham MacGregor, estimate that reducing sodium intake by 1,200 mg per day would reduce stroke deaths by about 13 percent, or 21,000 per year in the United States, and reduce coronary heart disease deaths by almost 10 percent – or 46,800, for a total of 68,000 lives.⁵⁹ Halving sodium consumption from about 4,000 to 2,000 mg would save roughly 113,000 lives per year.
- A Finnish study of more than 3,000 25- to 64-year-olds found that a 2,300 mg higher sodium intake was associated with the following increases in death rates: coronary heart disease, 51 percent; total cardiovascular disease, 45 percent; and all-cause mortality, 26 percent.⁶⁰

55. Prospective Studies Collaboration, op cit.

56. Cutler JA, Follmann D, Allender PS. op cit. Cutler J. Pers. comm. Dec. 27, 2004.

57. Cook NR, Cohen J, Hebert PR, et al. Implications of small reductions in diastolic blood pressure for primary prevention. *Arch Intern Med.* 1995; 155:701–9.

58. Stamler J, Stamler R, Neaton JD. Blood pressure, systolic and diastolic, and cardiovascular risks. *Arch Intern Med.* 1993; 153:598–615.

59. He FJ, MacGregor GA. How far should salt intake be reduced? *Hypertension.* 2003; 42:1093–9. (CSPI averaged the percentage reductions based on systolic and diastolic blood pressures.)

60. Tuomilehto J, Jousilahti P, Rastenyte D, et al. Urinary sodium excretion and cardiovascular mortality in Finland: a prospective study. *Lancet.* 2001;357:848–51.

Considering that 650,000 Americans die each year of coronary heart disease and stroke,⁶¹ that study implies that halving daily sodium consumption to 2,000 mg would save over 200,000 lives per year.

● Claude Lenfant, then the director of NHLBI, Stephen Havas at the University of Maryland School of Medicine, and Edward Roccella, also at NHLBI, estimate that a 50 percent reduction in sodium would “result in at least a 5 mm Hg decrease in systolic blood pressure levels, a 20 percent reduction in the prevalence of hypertension, and 150,000 fewer deaths [per year].”⁶² The authors note that the benefits of reducing sodium might be even greater, because high-sodium diets appear to be harmful in ways other than raising blood pressure.⁶³

The estimates from the several studies vary somewhat, and the experts will continue to debate the exact number of lives that could be saved by lowering sodium. However, the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure concluded that the relationship of blood pressure to stroke, coronary heart disease, and end-stage renal disease is “strong, continuous, graded, consistent, independent, predictive, and etiologically significant.”⁶⁴ Virtually all hypertension experts agree that eating significantly less salt would save tens of thousands of lives each year. Eating an overall more healthful diet and losing weight in addition to lowering sodium levels would save tens of thousands more.

VI. Health Authorities Recommend Greatly Decreased Sodium Consumption

As a result of research conducted over the past 50 years, a consensus has emerged among cardiovascular (“CVD”) researchers that sodium has a major impact on heart disease and stroke. That consensus is reflected in the increasingly definitive and specific recommendations that have been made by HHS in its series of *Healthy People* reports. The first edition of *Healthy People*, published in 1979, states “it is not clear how much the range of salt intake current today in the United States contributes to the prevalence of hypertension, or how much would be achieved in prevention by a broad reduction in salt (sodium) use...”⁶⁵ In 2000, *Healthy People 2010* set a

61. National Heart, Lung, and Blood Institute. Morbidity and Mortality: 2004 Chartbook on Cardiovascular, Lung, and Blood Diseases. 2004. Chart 2-8.

62. Havas S, Roccella EJ, Lenfant C., op cit.

63. He J, Ogden LG, Vupputuri S, et al. Dietary sodium intake and subsequent risk of cardiovascular disease in overweight adults. *JAMA*. 1999;282:2027-34.

64. Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. The Sixth Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. *Arch Intern Med*. 1997; 157:2413–46.

65. 68 Fed. Reg. 41433 (July 11, 2003) at 41490 Table 12.

goal of increasing the proportion of people who consume 2,400 mg or less of sodium daily from 21 percent to 65 percent.⁶⁶

Since 1980, every edition of *Dietary Guidelines for Americans*, published by the USDA and HHS, has advised Americans to reduce their intake of sodium. In 2004, for the first time, the Dietary Guidelines Advisory Committee provided its own quantitative recommendation. In its report, that committee stated:

The relationship between salt (sodium chloride) intake and blood pressure is direct and progressive without an apparent threshold. Hence, individuals should reduce their salt intake as much as possible. In view of the currently high levels of salt intake, a daily sodium intake of less than 2,300 mg is recommended. Many persons will benefit from further reductions in salt intake, including hypertensive individuals, blacks, and middle- and older-aged adults.⁶⁷

The 2005 *Dietary Guidelines for Americans* report states that individuals with hypertension, blacks, and middle-aged and older adults should aim to consume no more than 1,500 mg of sodium per day. Others could consume up to 2,300 mg.

In 2004 the National Academy of Sciences' Institute of Medicine ("IOM") recommended an "Acceptable Intake" of sodium according to following schedule⁶⁸:

- People under 50: 1,500 mg
- People 50–70: 1,300 mg
- People over 70: 1,200 mg

The FDA has long recommended that individuals should consume no more than 2,400 mg of sodium per day (equivalent to about 6 grams of salt), the Daily Value shown on Nutrition Facts labels. But the evidence that sodium contributes to high blood pressure in salt-sensitive persons has gotten stronger, and such authoritative committees (IOM) and the Dietary Guidelines Advisory Committee have recommended lower intakes. Though a small percentage of individuals appear to be relatively insensitive to the hypertensive effects of sodium, a sizeable

66. Longwell LS. Pers. comm. Sept. 27, 2004.

67. U.S. Department of Health and Human Services and U.S. Department of Agriculture. Report by the Dietary Guidelines Advisory Committee. 2004. At D-10:8. Some members of the committee may have felt that a lower recommended level would be hard to follow because of the lack of low-sodium foods. *The Wall Street Journal* (Aug. 17, 2005) at D1. Ultimately, HHS and USDA set a lower recommended level of 1,500 mg per day for blacks, people with hypertension, and middle-aged and older adults. Our proposal would ensure that over the next decade the sodium content of processed foods would gradually decline and that consumers would gradually be accustomed to the lower sodium levels.

68. Institute of Medicine, National Academies. *Dietary Reference Intakes: Water, Potassium, Sodium, Chloride, and Sulfate*. Washington, D.C.: National Academies Press, 2004. P. 6-38.

percentage of the population is salt-sensitive to varying degrees, and so public health officials recommend that sodium levels in the general food supply be reduced.

The most specific plan for reducing sodium levels has come from the American Public Health Association. In 2002, it adopted a policy resolution calling for a 50 percent reduction in sodium in processed and restaurant foods over the next 10 years, or 5 percent per year.⁶⁹ That bold goal was endorsed in 2003 by the broader health community, including the NIH. The Seventh Report of the Joint National Committee on the Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (“JNC 7”) “endorses the American Public Health Association resolution that the food manufacturers and restaurants reduce sodium in the food supply by 50% during the next decade.”⁷⁰ The JNC 7 report, as it is called, was approved by the NHBPEP Coordinating Committee. That committee is chaired by the director of the NHLBI and consists of representatives from 39 major medical and professional organizations, health charities, several institutes of the National Institutes of Health, and the Centers for Disease Control and Prevention (“CDC”).

Finally, at the global level, in 2003, in “Diet, Nutrition, and the Prevention of Chronic Diseases,” the World Health Organization (“WHO”) recommended that sodium levels be lower than 2,000 mg per day.⁷¹ In 2004, the WHO urged nations to consider a variety of actions to achieve that and other dietary recommendations, including encouraging “healthy diets at schools and limit[ing] the availability of products high in salt, sugar, and fats.”⁷² The WHO also calls on food processors to reduce the salt content of processed foods and to be careful about marketing foods high in salt and other unhealthful ingredients to children.⁷³

69. Resolution: Reducing the Sodium Content of the American Diet. Washington, DC: American Public Health Association, 2002, cited in Havas S, Rocella EJ, Lenfant C. Reducing the public health burden from elevated blood pressure levels in the United States by lowering intake of dietary sodium. *Am J Pub Health*. 2004; 94:19-22.

70. Chobanian AV, Bakris GL, Black HR, et al. The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. *JAMA*. 2003; 289:2560-72.

71. World Health Organization. Diet, Nutrition and the Prevention of Chronic Diseases. Geneva. 2003. P. 85.

72. 57th World Health Assembly. Global Strategy on Diet, Physical Activity, and Health. Agenda item 12.6. Geneva, World Health Organization, May 22, 2004.

73. Ibid.

VII. Salt Levels Can Be Reduced Significantly In Most Processed Foods Without Jeopardizing Taste or the Public Health.

In the early 1980s, several companies – McDonald's, Quaker, and Campbell's Soup Company – made public commitments to reduce sodium levels.⁷⁴ CSPI recently compared the sodium content of products made by those companies in both 1984 and 2004.⁷⁵ We found that the sodium content of 16 McDonald's products (including the Egg McMuffin and Filet-o-Fish) declined by an average of 9 percent, 8 Quaker products (including instant oatmeals and Aunt Jemima pancake mixes) declined by 23 percent, and 13 Campbell soups declined by 10 percent. Although those voluntary reductions are modest, they indicate that other companies could lower their sodium levels, too.

Comparing sodium levels in packaged foods suggests one strategy for reducing sodium levels without jeopardizing public health. Comparisons reveal that sodium levels vary widely from brand to brand of the same product (see attachment 2).⁷⁶ In many categories of food, some brands have 50 percent to 200 percent more sodium than competing brands. In many cases, companies that market higher-sodium products should be able to lower sodium levels to those used by some of their competitors. (We understand that at least one large manufacturer is reviewing and seeking to lower sodium levels across its entire product line.)

In 1999 a major supermarket chain (Sainsbury's) in the United Kingdom started reducing sodium levels in its store-brand foods by 10 percent to 15 percent. The chain claims to have saved the equivalent of almost 400 tons of salt per year.⁷⁷

In 2003, the British government's Food Standards Agency began waging a vigorous public campaign to encourage food manufacturers to reduce sodium levels in their products. The government's goal is to reduce sodium consumption by one-third over the next five years, from 3,780 mg (including salt added at the table) to 2,480 mg.⁷⁸ The agency identified the sodium content of 48 categories of food and the contribution each category makes to overall sodium consumption and specified a target for lowering the sodium content in each category of food. For example, the agency proposed a 55 percent reduction in the sodium content of canned soups (which contribute 2.6 percent of sodium to the average diet), a 29 percent reduction in cheeses (which contribute 3.8 percent of sodium to the average diet), and an 81 percent reduction in canned vegetables (which contribute 0.8 percent of sodium to the average diet).

74. These commitments may have flowed from a meeting the Secretary of Health and Human Services and the FDA Commissioner held with the food industry on June 30, 1981. 47 Fed. Reg. 26592.

75. Unpublished.

76. Jacobson M. Salt Assault: brand name comparisons of processed foods. CSPI. August 17, 2005. <http://www.cspinet.org/new/200508171.html>; accessed August 17, 2005.

77. www.sainsburys.co.uk/food_issues/ (accessed July 27, 2005).

78. See various documents at www.food.gov.uk.

In addition to a paid mass-media campaign to inform consumers, the British government's efforts have included publicizing widely disparate levels of sodium in different brands of pizza, baked beans, and other processed foods and criticizing such prominent companies as Nestle, Heinz, and McDonald's for marketing foods that are unnecessarily high in sodium. That approach is spurring at least some companies to reduce sodium levels (for example, Kraft lowered the sodium content of Oscar Mayer Lunchables by 20 percent in the United Kingdom).⁷⁹ We question the breadth, depth, and permanence of those changes, though, because the UK, at least initially, is not taking any regulatory actions.

VIII. The FDA Has Ample Legal Authority to Restrict the Amount of Sodium in Processed Foods, to Require a Health Warning on Packaged Salt, and to Reduce the Daily Value for Sodium.

As discussed above (in section III.D.), in 1982 the FDA decided not to revoke the GRAS status of sodium. The FDA also said in 1982 that there were many "prior sanctions" for salt.⁸⁰ However, the FDA's regulations provide that ingredients:

which have been considered in the past by the Food and Drug Administration to be safe under the provisions of section 402(a)(1) [of the Federal Food, Drug, and Cosmetic Act], or to be generally recognized as safe for their intended use, or to have prior sanction or approval, or not to be food additives under the conditions of intended use, must be reexamined in the light of current scientific information and current principles for evaluating the safety of food additives if their use is to be continued.⁸¹

A. Salt is no longer "Generally Recognized As Safe" by scientists and so is a food additive within the meaning of section 201(s) of the Federal Food, Drug, and Cosmetic Act.

The regulatory scheme established by the Federal Food, Drug, and Cosmetic Act ("FFDCA") divides food ingredients into those that are "food additives" and those that are not. This distinction is important because section 409(a)(2) of the FFDCA provides that the former may be legally used only if the FDA has issued a regulation "prescribing the conditions under which such additive may be safely used."

Section 201(s) of the FFDCA provides, in pertinent part, a two-part test for defining when an ingredient is a food additive:

any substance [1] the intended use of which results or may reasonably be expected to result, directly, or indirectly, in its becoming a component or otherwise affecting the characteristics of any food...[and] [2] if such substance is not generally recognized,

79. Food Standards Authority. Salt in Processed Foods.
<http://www.food.gov.uk/healthiereating/salt/saltmodel>; accessed August 17, 2005.

80. 47 Fed. Reg. at 26593.

81. 21 C.F.R. 170.6(c)

among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use of food) to be safe under the conditions of its intended use...

Section 201(u) of the FFDCA says “The term ‘safe,’ as used in paragraph [201](s)...has reference to the health of man or animal.”

There can be no doubt that salt meets the first part of this legal test, as its purpose is to affect the taste of food and – in some foods – prevent the growth of pathogens.

As discussed above (in section III.B.), in 1979 the FASEB concluded that there was insufficient evidence to find that salt is GRAS at the consumption levels then in effect. The scientific evidence (discussed above in Sections IV and V) confirms the FDA’s findings in 1982 and 2005 (discussed in sections III.D. and III.I) that salt also meets the second part of the legal definition of a food additive because it contributes to high blood pressure. Salt, therefore, can no longer be considered GRAS. Those who wish to continue the unrestricted use of salt can no longer meet their burden⁸² of showing that it is GRAS “under the [current] conditions of its intended use.”

Consequently, the FDA should amend its regulations to revoke the GRAS status of salt and reclassify it as a food additive.

B. The FDA can legally amend any prior sanctions for salt in order to provide for its safe use.

Section 201(s)(4) of the FFDCA also excludes from the definition of a food additive “any substance used in accordance with a sanction or approval granted prior to” September 6, 1958, and (as noted above) in 1982 the FDA said that there are many prior sanctions for salt.

However, relying on section 402 of the FFDCA,⁸³ the FDA’s regulations provide that

Based upon scientific data or information that shows that use of a prior-sanctioned food ingredient may be injurious to health,...the Commissioner will establish or amend an

82. The FDA’s regulations provide that the Commissioner, after reviewing the evidence, will revoke the GRAS status of an ingredient “[i]f he concludes that there is a lack of convincing evidence that the substance is GRAS or is otherwise exempt from the definition of a food additive in section 201(s) of the Act...” 21 C.F.R. 170.38(b)(3). Citing *United States v. Article of Food and Drug Consisting of Coli-Trol* 80, 518 F.2d 743,745 (5th Cir. 1975), the FDA said in 1997 that the proponent of an exemption from the definition of a food additive “has the burden of proving that the use of the substance is ‘generally recognized’ as safe.” 62 Fed. Reg. 18937 (April 17, 1997) at 18939.

83. Section 402(a) provides, in pertinent part, that a food is adulterated if it contains an ingredient “which may render it injurious to health.”

applicable prior sanction regulation to impose whatever limitations or conditions are necessary for the safe use of the ingredient, or to prohibit use of the ingredient.⁸⁴

The scientific evidence (discussed above in sections IV and V) indicates that those prior sanctions for salt should be amended to bring about the reduction in sodium consumption that is necessary to protect the public health.

C. The FDA can legally set limits on the amount of sodium in processed foods unless such a reduction would jeopardize the public health.

Section 409(a)(2) of the FFDCa bars the use of a food additive unless “there is in effect, and it and its use or intended use are in conformity with, a regulation issued under this section prescribing the conditions under which such additive may be safely used.” Section 409(c)(1)(A) of the FFDCa says that those conditions may include “any...labeling or packaging requirements for such additive deemed necessary by him to assure the safety of such use.” Section 409(d) of the FFDCa provides that “The Secretary may at any time, upon his own initiative, propose the issuance of a regulation prescribing, with respect to any particular use of a food additive, the conditions under which such additive may be safely used, and the reasons thereof.” Section 201(u) of the FFDCa says “The term ‘safe,’ as used...in sections 409, 512, 571, and 721, has reference to the health of man or animal.”

Those statutory provisions – along with section 402 of the FFDCa (as it relates to prior sanctions) – clearly give FDA the authority to set a ceiling on the amount of sodium in processed foods unless the food manufacturer can show that such a ceiling would jeopardize the public health.

D. The FDA can legally require a health warning on packaged salt.

Those statutory provisions also clearly give FDA the authority to require on packaged salt a warning about the health dangers of high levels of salt consumption. The FDA has required additional label information for the retail food sales of other food ingredients or of foods in which they are used, such as aspartame,⁸⁵ olestra,⁸⁶ and whole fish protein concentrate.⁸⁷

84. 21 C.F.R. 181.1(b).

85. 21 C.F.R. 172.804(d) The label of any food containing aspartame shall say “PHENYLKETONURICS: CONTAINS PHENYLALANINE.”

86. 21 C.F.R. 172.867(e) (2002 edition). The label for any food containing olestra should say “THIS PRODUCT CONTAINS OLESTRA. Olestra may cause abdominal cramping and loose stools. Olestra inhibits the absorption of some vitamins and other nutrients. Vitamins A, D, E, and K have been added.” The requirement for a notice on products containing olestra was revoked in 2003. 68 Fed. Reg. 46363 (August 5, 2003).

87. 21 C.F.R. 172.385(f)(3). The labels of manufactured foods containing the additive shall say in the ingredient list “whole fish protein concentrate.”

Moreover, section 403(a) of the FFDCa says, in pertinent part, that a “food shall be deemed to be misbranded if its labeling is....misleading in any particular.” Section 201(n) of the FFDCa provides, in pertinent part, “in determining whether the labeling...is misleading there shall be taken into account (among other things) not only representations made or suggested...but also *the extent to which the labeling...fails to reveal... consequences which may result from the use of the article to which the labeling relates...under such conditions of use as are customary or usual.*” (emphasis added)

The FDA’s regulations provide that affirmative disclosure of material facts pursuant to those statutory requirements may be required through regulations.⁸⁸ The FDA has said that it “has required special labeling in cases where information is necessary to ensure that consumers are aware of special health risks associated with consumption of a particular product.”⁸⁹ For example, the FDA has issued final regulations concerning certain ingredients:

- the term “milk derivative” must follow the ingredient declaration of sodium caseinate, which is GRAS,⁹⁰ when it is used in a food product labeled “non-dairy;”⁹¹
- food labels must disclose the presence of FD&C Yellow No. 5.⁹² The FDA said that such labeling was necessary because of the “life-threatening nature of the reaction in those people who are sensitive to the dye;”⁹³ and
- in 1996 the FDA required a warning label on foods containing olestra even though it had determined that olestra was a safe food additive.⁹⁴

88. 21 C.F.R. 1.21(b).

89. 61 Fed. Reg. 3117 (January 30, 1996) at 3160.

90. 21 C.F.R. 182.1748.

91. 21 C.F.R. 101.4(d). The Food Allergen Labeling and Consumer Protection Act of 1990, Title II of P.L. 108-282, requires that a milk derivative be so identified (along with derivatives of seven other major allergens) for all foods.

92. 21 C.F.R. 74.705(d)(2). Section 7 of the Nutrition Education and Labeling Act of 1990, P.L. 101-535, amended section 403(i) of the FFDCa to require that all colors certified under what is now section 721(c) of the FFDCa must be shown as a separate ingredient.

93. 45 Fed. Reg. 60419 (September 12, 1980) at 60419.

94. In 1996 the FDA required that the label for any food containing olestra should say “THIS PRODUCT CONTAINS OLESTRA. Olestra may cause abdominal cramping and loose stools. Olestra inhibits the absorption of some vitamins and other nutrients. Vitamins A, D, E, and K have been added.” 21 C.F.R. 172.867(e) (2002 edition). The requirement for a notice on products containing olestra was revoked in 2003, in part because the FDA determined that evidence gathered in consumer surveys after 1996 showed that there was “a high degree of awareness among the public” about the possible effects of

The FDA also relied on the statutory misbranding provisions when in July 1990 it issued a proposed rule to expand the scope of mandatory nutrition labeling.⁹⁵ The FDA said that it had concluded that the misbranding provisions of the FFDCA “can be reasonably interpreted to require nutrition labeling on all foods that are meaningful sources of nutrition.”⁹⁶ However, the FDA acknowledged at that time that it had made a contrary statement in 1981 and that it had acknowledged in 1979 and 1989 that there were legal questions about its authority.⁹⁷ The final nutrition labeling regulations relied on the NLEA. The Committee on Energy and Commerce said that “the purpose of this legislation [the NLEA] is to clarify and to strengthen the Food and Drug Administration’s legal authority to require nutrition labeling on foods...”⁹⁸

It is certainly material information for consumers that high levels of salt consumption can increase blood pressure, thereby increasing the consumer’s risk of coronary heart disease, stroke, congestive heart failure, and kidney disease.

E. The FDA Can Legally Reduce the Daily Value for Sodium.

As discussed above (in section III.F.), in 1993 the FDA set a recommended Daily Value (“DV”) for sodium of 2,400 mg. The FDA chose 2,400 mg. because it was consistent with other Federal agency recommendations and was a feasible goal in light of the variety of foods then available to consumers. *The Dietary Guidelines for Americans 2005* recommends 2,300 mg. for young non-hypertensive white adults and 1,500 mg. for people with hypertension, blacks, and middle-and-older-aged adults.

Section 2(a) of the NLEA provides that the FDA may require food-labeling information for sodium (and eight other specific nutrients) if the FDA determines that providing such information “will assist consumers in maintaining healthy dietary practices.” Section (2)(b)(1)(A) of the NLEA directs that the FDA’s “regulations shall require the required information to be conveyed to the public in a manner which enables the public to readily observe and comprehend such information and to understand its relative significance in the context of a total daily diet.”

The House of Representatives’ Committee on Energy and Commerce explained that the former statutory provision gives the FDA “the discretion to take new information into account

olestra. 68 Fed. Reg. 46363 (August 5, 2003) at 46387.

95. At that time nutrition labeling was mandatory “only when a nutrient has been added to the food, or when the labeling or advertising for the food includes a claim or other representation about the food’s nutritional properties, its fat or caloric content, or its usefulness in the daily diet.” 55 Fed. Reg. 29487 (July 19, 1990) at 29491.

96. 55 Fed. Reg. 29487 (July 19, 1990) at 29491.

97. 55 Fed. Reg. at 29491 fn. 1.

98. H.R. Rept. 101-538, 101st Cong., 2d Sess (June 13, 1990) at 7.

and the ability to require that the nutrition label of foods be consistent with new research and other information.”⁹⁹ The Committee explained that the latter statutory provision means that “one way that this could be accomplished would be to include information about the recommended daily intake on the label.”¹⁰⁰

Those two statutory provisions and their legislative histories provide the legal authority for the current DV for sodium and the authority to reduce that Daily Value in order to protect those groups of Americans who are most likely to be sodium-sensitive. We urge the FDA to adopt a DV of 1,500 mg, because that is the recommended maximum intake for roughly one-half the adult population (people with hypertension, blacks, and middle-aged and older people).¹⁰¹ When recommended consumption levels vary among population groups, the FDA has typically been conservative, choosing a DV that is most protective.¹⁰²

IX. Conclusion

For the reasons stated above, the FDA should immediately initiate a rulemaking to revoke the GRAS status of salt, to gradually reduce the amount of sodium in processed foods (avoiding food-safety risks) to achieve a 50 percent reduction in the weighted-average sodium content of such foods over a ten-year period, to require a health warning on packaged salt, and to reduce the Daily Value for sodium.

X. Environmental Impact

The action requested is subject to a categorical exclusion under 21 C.F.R. 25.30 and 25.32 and therefore does not require the preparation of an environmental assessment.

99. *Id.* at 14.

100. *Id.* at 18.

101. The Institute of Medicine divided adults into three age groups – 19-50, 51-70, and over 70 – and recommended progressively lower daily sodium and salt consumption levels for each group. *Dietary Reference Intakes, Water, Potassium, Sodium, Chloride, and Sulfate* (Institute of Medicine of the National Academies 2004) at 6-36 to 6-39. In 2003 there were 83 million Americans over the age of 49; there were also 17 million Blacks age 20-49. *Statistical Abstract of the United States, 2004-2005* (United States Census Bureau 2004) at Table 14. Thus, middle-aged and older people and other adult Blacks comprised about 48 percent of the 2003 population of 210 million people age 20 and above.

102. For instance, the recommended daily consumption of iron is 18 mg for women and 10 mg for men. The FDA set the DV at 18 mg.

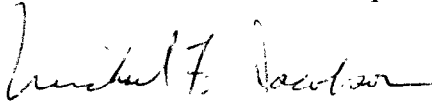
XI. Economic Impact

No statement of the economic impact of the requested action is presented because none has been requested by the Commissioner.¹⁰³

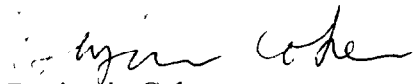
XII. Certification

The undersigned certify that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and it includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully submitted,



Michael F. Jacobson, Ph.D.
Executive Director



Benjamin Cohen
Senior Staff Attorney

Attachments: Attachment 1: Table of NHANES and CSFII sodium intakes
Attachment 2: Salt Assault (CSPI report)

103. 21 C.F.R. 10.30(b).